United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: D-54
● Original
○ Amendment

Contract Number: EP-C-09-027	Contract Period Base: 4/1/09 - 3/31/10 Option Period No. 0	SF Site Name:

Title of Work Assignment: Decontamination Efficacy of Vaporous Hydrogen Peroxide for Environmental Surfaces Contaminated with Bacterial Spores

Suggested Source:	Specify Section & Paragraph of Contract SOW:
Purpose: ● Work Assignment Initiation ○ Work Assignment Close-Out ○ Work Assignment Amendment ○ Incremental Funding ○ Work Plan Approval	Period of Performance From: 11/23/2009 To: 03/31/2010
Comments: see attached SOW	QA Category (check one) ○ I Enforcement ○ II Standard Setting ○ III Technology Development ● IV Proof of Concept ○ N/A

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO 22 (Max 2) ☐ Superfund ☐ Non-Superfund

Accounting and Appropriations Data

	DCN (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount	Sites/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									

Authorized Work Assignment Ceiling

Contract Period:		Cost/Fee	LOE
Previously Approved	New		
This Action			384
Total			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Attwood, Brian Brian C Attwood 11/6/2009 (Signature) (Date)	Branch / Mail Code: NHSRC-DCMD / E343-06 Phone Number: (919) 541-5626 Fax Number: (919) 541-0496
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Project Officer Name: Diane L. Pierce Diane L Pierce 11/19/09 (Signature) (Date)	Branch/Mail Code: NRMRL-APPCD/E343-01 Phone Number: (919) 541-2708 Fax Number: (919) 541-1536
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STATEMENT OF WORK WA 0-54

DECONTAMINATION EFFICACY OF VAPOROUS HYDROGEN PEROXIDE FOR ENVIRONMENTAL SURFACES CONTAMINATED WITH BACTERIAL SPORES

OMIS DCMD 3.26A

U.S. ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HOMELAND SECURITY RESEARCH CENTER
DECONTAMINATION AND CONSEQUENCE MANAGEMENT DIVISION

I. TITLE

Decontamination Efficacy of Vaporous Hydrogen Peroxide For Environmental Surfaces Contaminated With Bacterial Spores

II. PERIOD OF PERFORMANCE

The period of performance for the work under this work assignment shall be from date of CO approval through March 31, 2010.

III. SUMMARY OF OBJECTIVES

This work shall estimate the occurrence and potential reduction of viable bacterial spores (i.e, effectiveness) on various surfaces exposed to vaporous hydrogen peroxide. The work will entail the preparation of the materials to be exposed and their exposure. The anticipated deliverable will be the contamination reduction data presented as a function of material, exposure time, and peroxide concentration.

IV. RELEVANCE

This project supports the mission of the Decontamination and Consequence Management Division (DCMD) within the U.S. Environmental Protection Agency's (U.S. EPA) National Homeland Security Research Center (NHSRC) by providing relevant information pertinent to the decontamination of contaminated areas resulting from an act of terrorism. The project supports the NHSRC's strategic goals as described in detail in the Homeland Security Research Multi-year Strategic Plan (draft, November 26, 2008). Specifically, the project is relevant to Long-Term Goal 2 (LTG-2) which states, "The Office of Solid Waste and Emergency Response (OSWER) and other clients use homeland security research program products and expertise to improve the capability to respond to terrorist attacks affecting buildings and the outdoor environments."

V. BACKGROUND

Under Homeland Security Presidential Directive (HSPD)-10, the U.S. Department of Homeland Security (DHS) is tasked to coordinate with other appropriate Federal departments and agencies, to develop comprehensive plans which, "provide for seamless, coordinated Federal, state, local, and international responses to a biological attack." As part of these plans, the U.S. EPA, in a coordinated effort with DHS, is responsible for "developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities" to mitigate the risks of contamination following a biological weapons attack.

NHSRC provides expertise and products that can be widely used to prevent, prepare for, and recover from public health and environmental emergencies arising from terrorist threats and incidents. Within NHSRC, DCMD's decontamination research program's goal is to provide expertise and guidance on the selection and implementation of decontamination methods and provide the scientific basis for a significant reduction in the time and cost of decontamination events. The NHSRC's research supports OSWER and OPP. OSWER, through its Special Teams which includes the NDT, supports the emergency response functions carried out by the Regional Offices. OPP supports the decontamination effort by providing expertise on biological agent inactivation and ensuring that the use of pesticides in such efforts is done in accordance with FIFRA. Close collaboration between the different program offices having homeland

security responsibilities is sought in order to rapidly increase the U.S. EPA's capabilities to help the Nation recover from a terrorist event involving the intentional release of chemical, biological, or radiological (CBR) materials. Such collaborations are fostered through efforts such as TRIO.

In 2001, the introduction of a few letters containing anthrax spores into the U.S. Postal Service system resulted in the contamination of several facilities. Although most of the facilities in which these letters were processed or received in 2001 were heavily-contaminated, they were successfully remediated with approaches such as fumigation with chlorine dioxide or VHP®. Since that time, STERIS Corporation's VHP process has been registered as a sterilant with the EPA. Although the VHP showed adequate biodecontamination capability on the porcelain penicylinders and silk suture loops used in the registration process, its efficacy for contaminated building materials is largely unknown.

VI. SCOPE

The purpose of this project is to determine the effectiveness of vaporous hydrogen peroxide for the decontamination of different building material surfaces contaminated with bacterial spores. Coupons of a variety of materials contaminated with aerosol-deposited bacterial spores shall be decontaminated using vaporous hydrogen peroxide. The effectiveness of this method shall be determined as a function of the operational parameters. These parameters are the exposure time and the concentration of hydrogen peroxide in the vapor phase. In addition to the in-chamber testing, this project will also involve testing the efficacy of VHP and other technologies for the decontamination of HVAC ductwork contaminated with bacterial spores.

VII. TECHNICAL APPROACH

The general approach that shall be used to meet the objectives of this project is as follows, as briefly mentioned in the Section VI:

- contamination of materials via aerosol deposition of bacterial spores using the procedure to be provided by the U.S. EPA for this study;
- assessment of contamination using positive control coupons;
- application of the prescribed decontamination procedures to test coupons;
- assessment of residual contamination on test coupons; and
- determination of decontamination effectiveness as measured by log reduction from the surfaces;

Decontamination can be defined as the process of inactivating or reducing a contaminant in or on humans, animals, plants, food, water, soil, air, areas, or items through physical, chemical, or other methods to meet a cleanup goal. In terms of the surface of a material, decontamination can be accomplished by physical removal of the contamination or via inactivation of the contaminant with antimicrobial chemicals. Physical removal could be accomplished via *in situ* removal of the contamination from the material or physical removal of the material itself (i.e., disposal). Similarly, inactivation of the contaminant can be done *in situ* or after removal of the material for ultimate disposal. During the decontamination activities following the results of the 2001 anthrax incidents, a combination of removal and *in situ* decontamination was used. The balance between the two was facility dependent and factored in many issues (e.g., physical state of the facility); one factor was that such remediation was unprecedented for the United States Government (USG) and no technologies had been proven for such use at the time. The cost of

disposal proved to be very significant and was complicated by the nature of the waste (e.g., finding an ultimate disposal site). Since 2001, a primary focus for facility remediation has been on improving the confidence in *in situ* decontamination methods and evaluating waste treatment options to be able to provide information necessary to optimize the decontamination/disposal paradigm; this optimization has a very significant impact on reducing the cost of and time for the remediation effort.

The technical approach to be used throughout this study shall be developed considering the background information provided in Section V and this section. In this study, coupons of select materials shall be loaded with spores using a deposition device that shall be provided to the contractor by the U.S. EPA Work Assignment Manager (EPA WAM). The coupons of each material shall be circular with a diameter of 18 mm; the thickness will vary for each material. Positive control coupons (i.e., contaminated with spores but untreated) shall be used to determine the pre-treatment (pre-decontamination) loading on each coupon type. Coupons shall be fumigated as detailed in Section XI. After fumigation and aeration, sampling shall be performed on the treated and positive control coupons. Procedural blank coupons (i.e., uninoculated coupons; negative controls) shall also be included in order to monitor for cross-contamination. All samples shall be analyzed for the quantitative determination of viable spores.

All sample analysis is outside of the scope of this work assignment. Samples shall be transferred to the National Risk Management Research Laboratory's (NRMRL) Air Pollution Prevention and Control Division's (APPCD) Microbiology Lab for analysis under a separate work assignment. The coupon fabrication is also outside the scope of this work assignment. The materials shall be prepared by the NRMRL/APPCD Machine Shop under a separate work assignment or will be provided by the EPA WAM.

VIII. AFFORDABILITY

Components of this study are expected to be somewhat labor intensive; the decontamination processes, sampling, and laboratory assays will require extensive human resources. Relative to the labor costs, only a minimal amount of expendable materials are required to be purchased by the contractor for use in this effort.

IX. TECHNICAL RISK

The technical risk involved in this project is thought to be minimal. The purpose of the effort is to provide information pertinent to the development of operational strategies for the decontamination methods included in the study. Hence, all information obtained in this project (whether intended or not) is expected to be significantly relevant to this purpose.

X. FACILITIES AND MATERIALS

All work on this project described in this statement of work (SOW) shall be performed at the U.S. EPA's facilities located at 109 T.W. Alexander Dr., Research Triangle Park, NC in the COnsequence ManageMent ANd Decontamination Evaluation Room (COMMANDER) located in H130.

XI. TASKS

The effort described in this SOW shall be performed in two tasks as generally described in Section VI.

Task 1:

The purpose of testing under this task is to determine the effectiveness of VHP fumigation for the decontamination of select building materials contaminated with bacterial spores.

A Category 3/Applied Research QAPP shall be developed by the U.S. EPA for this effort that provides details of the procedures to be used for each step listed above. The contractor shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this work assignment package (see Attachment #1 to the SOW) and the NHSRC QA requirement as defined in Attachment #2 to the SOW. The U.S. EPA shall prepare a QAPP in accordance with the type of research that is being conducted. The contractor shall review, recommend changes, and accept the QAPP within two weeks of receiving it from the EPA. Any required amendments to the QAPP shall be performed by the contractor. The QAPP, including any amendments, must be approved by the U.S. EPA in writing (e.g., signature on the approval page) prior to the start of any work. Additional information related to QA requirements can be found at: http://www.epa.gov/quality/qs-docs/r5-final.pdf.

The contractor shall design an MS Excel data reporting sheet template prior to the start of any work that conveys all relevant information from a test. This template shall be approved by the EPA for use, prior to conducting any testing described in this SOW. All photographs and videos shall be properly documented, indicating the exact tests in which they were taken. A log (in MS Excel) of all photographs and videos shall be maintained with the electronic files. The log shall include a description of each photograph and video, and include the test number and date. All electronic files shall be stored in a project folder set up on the EPA's DTRL share drive. All information relevant to a test (reporting sheet, digital photographs, videos, log file) shall be transmitted to the EPA WAM within 1 week from the completion of the sample analysis. These data shall have been QA/QC'd by the contractor prior to transmission. Transmission shall occur via e-mail to the EPA WAM informing him/her that the data are ready for viewing.

Testing shall be conducted in the COnsequence ManageMent ANd Decontamination Evaluation Room (COMMANDER) located in H130. This stainless steel (Type 316) test chamber has internal dimensions of 10 ft wide × 8 ft deep × 10 ft high. It is equipped with an airlock containing a decontamination shower. The general procedure for each test in this task shall be as follows:

1. Sterilization of all coupons and materials needed for the test; verification is required.
2. Contamination of test and positive control coupons with the procedure provided by the EPA WAM. Contamination shall be done with *Bacillus subtilis* ATCC 19659 (another BSL-1 level microbe or *Geobacillus* species may substituted by the EPA WAM). The procedure is expected to include using a single puff from a metered-dose inhaler (MDI) for each coupon into a surface deposition device to be provided by the EPA WAM.
3. Test coupons and blank coupons (negative controls) will be loaded into the COMMANDER chamber.

4. The fumigation shall be performed using the STERIS VHP 1000ED according to the parameters in Table 1. Exposure times in later tests are subject to change based on the results of the earlier tests. Coupons will begin the test runs protected from the VHP and successively exposed in "reverse time points" from the end of the fumigation. For example, in test one, one set of coupons will be exposed 240 prior to aeration, another 120 minutes prior to aeration, etc. Coupons will remain exposed during the course of aeration. minutes
5. After the maximum exposure time is reached, the chamber shall be immediately aerated until vaporous hydrogen peroxide concentrations are sufficiently low for personnel to enter the COMMANDER.
6. The test coupons, procedural blanks, and positive controls shall be transferred to the APPCD Microbiology Lab in sterile primary independent packaging within sterile secondary containment containing logical groups of samples. All samples shall be accompanied by a completed chain of custody form.

Further details regarding execution of the above steps shall be provided in the QAPP by the WAM. In addition to the steps outlined above, all test activities shall be fully documented during the activity via narratives in laboratory journals, the use of digital photography and video. The documentation should include, but not be limited to, record of time required for each decontamination step or procedure, visual observations during the procedures, any deviations from the test plans, physical impacts on the materials, and impacts on the decontamination or sampling personnel.

Table 1: Preliminary Test Matrix

Test	Concentration (ppm)	Exposure Times (min)	Materials (m=metal, w=wood, c=carpet, t=ceiling tile, p=wallboard paper)	Total # Coupons (including positive controls, negative controls, and test coupons)
1	250	60,90,120,240	m,w,c	67
2	400	15,30,60,120	m,w,c	67
3	250	60,90,120,240	t,p,m	67
4	400	15,30,60,120	t,p,m	67
5	250	60,90,120,240	m,w,c	67
6	400	15,30,60,120	m,w,c	67
7	250	60,90,120,240	t,p,w	67
8	400	15,30,60,120	t,p,w	67
9	250	60,90,120,240	t,p,c	67
10	400	15,30,60,120	t,p,c	67

Task 2:
The purpose of this task is to assemble a section of ductwork on the mezzanine level of H130 that will allow the WAM to conduct in-duct efficacy testing. This task shall be completed in the following steps:

1. The contractor shall design a layout of 24-inch diameter, insulated, galvanized steel ductwork to suspend from the ceiling on the second level of the mezzanine in H130.
2. Following approval by the WAM of the proposed layout, the contractor shall provide the WAM with a list of components that will need to be ordered.
3. The contractor will assemble the ductwork in H130 as designed.
4. The contractor will attach necessary fittings and install sensors as requested by the WAM.
5. The contractor will replace sections of ductwork and reconfigure the ductwork from its initial configuration as requested by the WAM.

XII. DELIVERABLE SCHEDULE

The deliverables previously described in this SOW with the scheduled due date are shown in Table 4. This is based on an anticipated work assignment initiation date of November 23, 2009. The dates in the parentheses are the anticipated deliverable dates based upon this start date. The actual deliverable schedule shall be updated based upon the actual start date.

Table 2: Deliverable Schedule

Task	Deliverable	Due Date
1	Amendment and/or approval of U.S. EPA provided QAPP	No later than 15 days after receiving the QAPP at the initiation of the work assignment
1	Data Reporting Sheet	Prior to start of test matrix
1	Electronic files from each test	One week after completion of all data analysis from the test

XIII. REPORTING REQUIREMENTS

a. The monthly invoice reports for this work assignment shall provide a detailed description of any equipment or expendables that have been purchased by the contractor for use on the projects discussed herein.
b. All data related to this project shall be stored on the U.S. EPA servers in the DTRL share folder.
c. Data transfer to the EPA WAM shall occur within one week from the completion of data analysis.
d. Reporting sheets shall be developed by the contractor, reviewed/approved by the EPA WAM, and hence used for all interim data reporting to the EPA WAM as required in this SOW.
e. All products developed under this SOW (e.g., the above mentioned technical report) must conform to the requirements of EPA's Handbook for Preparing Office of

Research and Development Reports (EPA/800/K-95/002). Substantive portions of this handbook can be found at www.epa.gov/nhsrc under the policy and guidance tab.

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM
Attachment 1 to the Statement of Work

I GENERAL INFORMATION

Title:	Decontamination Efficacy of Vaporous Hydrogen Peroxide for Environmental Surfaces Contaminated with Bacterial Spores	
Description:	material demand and efficacy studies for VHP	
Project ID:	DCMD 3.26A	
Status:	Original	
Number Ammended:		
QA Category:	IV	
Action Type:	Extramural	
Peer Review Category:	IV	
Security Classification:	Unclassified	
Project Type:	Applied Research	
QAPP Status 1:	Not Delivered	
QAPP Status 2:	Not Delivered	
QAPP Status 3:	Not Delivered	
Vehicle Status:	Existing Vehicle	
Vehicle Type:	Vehicle Number:	EPA-C-09-27
	Work Assignment Number:	TBD
	Delivery/Task Order Number:	na
	Modification Number:	na
	Other:	na

*If you are processing an **IAG** or **CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at http://www.epa.gov/quality/qs-docs/r5-final.pdf

Yes Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?

(If "No" then skip to Section IV, and sign the form.)

No Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

No Has a QAPP already been approved for the activities specified in the SOW?

Yes Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use by the contractor? (QA approval must be obtained before the contractor can start work.)

Provide the expected title for submission to QA staff for approval:

Decontamination Efficacy of Vaporous Hydrogen Peroxide for Environmental Surfaces Contaminated with Bacterial Spores

Provide the approximate date for submission to QA staff for approval:

11/23/2009

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

After Award Documentation

Not Applicable	Documentation of an organization's Quality System. QMP developed in accordance with:
Not Applicable	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with:
Other	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with: Explain: NHSRC QMP and attachment #2 to the SOW
na	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Not Applicable	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

11/9/2009		Ramona Sherman 11/17/09	
Brian Attwood NHSRC-DCMD Technical Lead Person	11/05/2009 Date	Eletha Roberts NHSRC-IO QA Staff Member	11/05/2009 Date

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives, shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site_specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination

between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 Describe how samples are uniquely identified.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain_of_custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA_approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NHSRC or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

Attachment # 2

NHSRC QA
To the Statement of Work
Requirements/Definitions List

EPAs Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qa-docs/r5-final.pdf

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
(2) an organizational chart showing the position of the QA function;
(3) delineation of the authority and responsibilities of the QA function;
(4) the background and experience of the QA personnel who will be assigned to the project; and
(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List
Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP: QAPP requirements for the specific project type (see below).

☒ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☒ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all

requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf.

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		